

REMARKS

Examiner Interview

Examiners Popa and Voitach ("Examiners") granted an Interview on June 13, 2007 to discuss the pending rejections in the instant case with Applicants' Representative. Applicants' Representative thanks Examiners for their courtesy and cooperation during the interview.

Applicants' Representative and Examiners discussed the pending claims rejections for this case. The responses below reflect and incorporate the recommendations and accords reached during the interview.

Rejection Under 35 USC § 112, second paragraph

Claims 80 and 94 have been rejected as being indefinite for the recitation of the phrase "one epitope-containing segment." Examiner recommends amending the claims to recite the phrase "an epitope-containing segment." The Applicants have amended the claims consistent with the Examiners recommendation. In view of the amendment the Applicants respectfully request that the rejection be withdrawn.

Rejection Under 35 USC § 112, first paragraph, Written Description

The Examiner has rejected Claims 94 for failing to comply with the Written Description requirement. Examiner notes that the subject claims were amended in response to Examiner's Enablement rejection of the previous Office Action. In pending Office Action Examiner is in agreement with Applicants' belief that the unamended claims were enabled. Therefore, Applicants have amended claims to restore the phraseology used prior to the previous Office Action. Examiner agreed during the Interview that this would result in the withdrawal of the pending Written Description rejection. In view of the amendment the Applicants respectfully request that the rejection of Claim 94 be withdrawn.

Additionally, Examiner states that the addition of the term "non-immortalized" to the claims constitutes new matter. Pending Office Action, top of page 4. Applicants submit that they have not added the term "non-immortalized" to the claims and request that the rejection be withdrawn.

Rejection Under 35 USC § 102(e)

The Examiner has rejected Claims 80 and 101 as being anticipated by Johnston, *et al.*, (US Patent no. 5,703,057) under 35 USC § 102(e). The Applicants respectfully disagree.

The Examiner states Johnston, *et al.*, teach an expression library immunization (ELI) where fragmented pathogen DNA is fused to DNA expressing mammalian genes such as ubiquitin. However, Johnston does not teach elements of the present invention as claimed. The Applicants have found that the mere use of a fusion sequence comprising one or more epitopes and ubiquitin, as taught by Johnston, *et al.*, does not result in optimal performance of the immunization of the subject animal. The Applicants have found through empirical research that “a fusion protein comprising a heat shock protein (e.g., ubiquitin), fused to an epitope or epitopes in a defined manner [as claimed] is useful for the stimulation of a specific immune response.” Pending application, ¶ [0012] (emphasis added). The bulk of the pending application is then directed towards the teaching and exemplification of the *defined manner* in which the fusion proteins of the present invention are made and used. For example, the present application teaches that the ubiquitin fusion proteins need to be tolerated both systemically (*i.e.*, tolerance by the immune system) and functionally (*i.e.*, behave in a manner analogous to wild-type ubiquitin) in order to function effectively as a fusion peptide immunogen. Pending application, paragraphs [0015] - [0017]. Applicants have found that only insertions at particular sites in ubiquitin are “tolerated.” Pending application, paragraph [0020]. Paragraphs [0020] through [0048] then teach in detail which fusion proteins are “tolerated” and the “defined manner” in which they are made. The pending claims are limited to such fusion proteins.

Applicants disagree with the Examiner’s assertion that the pending claims are anticipated by Johnson, *et al.* However, and solely to advance the Applicants’ business interests, Claim 80 has been amended to better define the metes and bounds of Applicants’ invention. Applicants reserve the right to prosecute the unamended claim or similar claim in the future.

Amended Claim 80 is directed towards a method of stimulating an immune response in an animal, the immune response being directed toward a fusion protein, the method comprising a) providing a DNA construct encoding a fusion protein selected from the group consisting DNA that encodes the fusion protein of the constructions of the amended claim. Johnston, *et al.*, do not teach any of these fusion proteins.

- i) a fusion protein comprising a heat shock protein fused to an epitope-containing segment, the epitope-containing segment *comprising two or more identical epitopes*,
- or,
- ii) a fusion protein comprising a heat shock protein fused to two or more non-contiguous epitope-containing segments, each epitope-containing segment comprising one or more *epitopes identical to the epitopes of the non-contiguous epitope-containing segments*,
- or,
- iii) a fusion protein comprising a heat shock protein fused to an epitope-containing segment comprising two or more identical or non-identical epitopes, the epitope-containing segments being fused to the fusion sites selected from the groups *consisting of the N-terminus and an internal fusion site*,
- or,
- iv) a fusion protein comprising a heat shock protein fused to an epitope-containing segment comprising one or more identical or non-identical epitopes, the epitope-containing segment *being fused to the N-terminus* of the heat shock protein, wherein one or more epitopes are recognized by an antibody to be detected.

It is required that an anticipatory reference teaches “each and every element as set forth in the claim.” MPEP 2131. Since, Johnston, *et al.*, do not teach the fusion proteins of Claim 80 (and dependent Claim 101) the cited reference cannot be considered anticipatory art for the present invention. Therefore, the Applicants respectfully request that the rejection be withdrawn.

Applicants have amended Claim 94 similarly to the manner in which Claim 80 has been amended solely to better define the metes and bounds of the present invention and to advance the Applicants’ business interests. Applicants reserve the right to prosecute the unamended Claim 94 or similar claim in the future.

Rejection Under 35 USC § 103

The Examiner has rejected Claims 80, 94 – 97 and 99 – 101 under USC § 103(a) as being unpatentable over Johnston, *et al.*, in view of Ferro, *et al.*, and Tang, *et al.*, and Sacca. The Applicants respectfully disagree with the Examiner's rejection.

A finding of obviousness requires the teaching of each element of the claimed invention in the prior art. MPEP 2143. As discussed above, Johnston, *et al.*, does not teach important elements of the present invention, as claimed. For example, Johnson, *et al.*, does not teach the expression constructs of the fusion proteins of the claimed invention. The secondary references cited by the Examiner do not teach or suggest these missing elements. Therefore, Applicants respectfully submit that Examiner has not made a *prima facie* case of obviousness for the present invention as claimed even when the cited references are viewed in combination and request that the rejection be withdrawn.

Rejection Under 35 USC § 103

The Examiner has rejected Claims 80, 94, 98, 100 and 101 under USC § 103(a) as being unpatentable over Johnston, *et al.*, in view of Hohlfeld, *et al.*, and Tang, *et al.* The Applicants respectfully disagree with the Examiner's rejection.

A finding of obviousness requires the teaching of each element of the claimed invention in the prior art. MPEP 2143. As discussed above, Johnston, *et al.*, does not teach important elements of the present invention, as claimed. For example, Johnson, *et al.*, does not teach the expression constructs of the fusion proteins of the claimed invention. The secondary references cited by the Examiner do not teach or suggest these missing elements. Therefore, Applicants respectfully submit that Examiner has not made a *prima facie* case of obviousness for the present invention as claimed even when the cited references are viewed in combination and request that the rejection be withdrawn.

Summary

In light of the above arguments and amendments, consideration of the subject patent application is respectfully requested. Applicants submit that all pending rejection have been overcome. Applicants request that the rejections be withdrawn and the application passed to allowance. Any deficiency or overpayment should be charged or credited to Deposit Account No. 500282.

Respectfully submitted,



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